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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Kirchholtes et al.

Serial No.: 09/787,215

Filed: May 17, 2001

For: HIGH PURITY COMPOSITION
COMPRISING (7 α , 17 α)-17-HYDROXY-7-
METHYL-19-NOR-17-PREGN-5(10)-EN-
20-YN-3-ONE

Examiner: S. Jiang

Group Art Unit: 1617

Attorney Docket No.: D/98409 US
(1963-5047US)

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Declaration Under 31 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Martinus A. Lunenburg, hereby declare that:

1. Solution ^1H and solid state ^{13}C NMR spectra were collected on two samples of (7 α , 17 α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one, which are designated as Samples A and B.

2. I have been asked to compare the two samples of (7 α , 17 α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one and to determine the chemical and physical or crystalline

purity of each sample. Specifically, I have been asked to determine the amount of (7 α , 17 α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one in the samples.

3. Both Samples A and B have a crystalline purity of greater than 98% of Form I of (7 α , 17 α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one, as determined by solid state ^{13}C NMR.

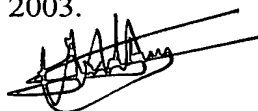
4. Sample A includes approximately 2.4% (7 α , 17 α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one, as indicated by the attached solution ^1H NMR. Sample B includes approximately 0.3% (7 α , 17 α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one, as indicated by the attached ^1H NMR.

5. The solid state ^{13}C NMR spectrum of Form 1 in Sas *et al.* (i.e. Fig. 5) does not indicate the chemical purity of the product with respect to the impurity (7 α , 17 α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one. Furthermore, the chemical purity cannot be determined given the signal to noise ratio in the relevant portion (between 200-205 ppm) of the spectrum.

6. From the foregoing NMR spectra, it can be seen that Samples A and B include different amounts of (7 α , 17 α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one. The NMR spectra also show that the chemical purity of Samples A and B is distinct whereas the crystalline purity is the same.

7. All statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment of both under Section 1001 of Title 18 U.S.C. and that such willful false statement may jeopardize the validity of the instant patent application or any patent issuing thereon.

Dated this 6th day of March, 2003.



NAME: Martinus A. Lunenburg